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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,980	12/27/2000	Elaine Lee	8600-0010	6822

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EXAMINER
BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No.	Applicant(s)	
	09/749,980	LEE, ELAINE	
	Examiner	Art Unit	
	Jessica R Baxter	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2002 and 03 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-11,14-19,21-32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) *25-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-11,14-19,21-24,31,32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

1. Claims 1, 2 and 33 were objected to because of various informalities. Correction is noted and the objections are withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-24 were rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Correction is noted and the rejection is withdrawn.

4. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term biodegradable is not supported in the specification. The specification, as filed only discloses that the composition is absorbable. It is unclear whether by absorbable, the applicant also means biodegradable. It is insufficient to incorporate the teachings of biodegradability with a reference in the specification. Claimed subject matter must be specifically disclosed in the specification. Mere reference to another application, patent, or publication is not an incorporation of anything therein to the application containing such reference for the purpose of disclosure as required by 112/1st.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 32 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 32 recites the limitation "the particular liquid embolic material" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 35 recites the limitation "the particulate material" in line 1. There is insufficient antecedent basis for this limitation in the claim.

9. Claims 31, 32, and 34-36 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Correction is noted and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3, 4, 11, 14, 18, 19, 21 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,980,550 to Eder et al. Eder discloses a vaso-occlusive device as claimed. Referring to claims 1, 3, 4 and 18, Eder discloses a vaso-occlusive composition that includes a vaso-occlusive member (column 3 lines 17-20), a thrombus-stabilizing molecule (column 6 lines 38-41), and a bioactive material in the form of cytokine VEGF (Column 5 line 64-Column 6

line 15 and Column 6 lines 38-48). Referring to claim 11, Eder discloses a device that has a bioactive material, a thrombus-stabilizing molecule or both the thrombus-stabilizing molecule and the bioactive material permanently bonded to the vaso-occlusive member (column 6 lines 38-48). Referring to claim 14, Eder also discloses a vaso-occlusive composition that has been plasma treated (column 3 lines 60-61). Referring to claims 19, 21 and 24, Eder discloses a method to occlude an aneurysm by administering the vaso-occlusive composition (column7 lines19-23 and lines 48-59) by administering the bioactive material VEGF.

12. Claims 1, 5-6, 16, 19 and 22 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,096,052 to Callister et al. Callister discloses the claimed occluding device. Referring to claims 1, 5 and 6, Callister discloses a device that comprises a vaso-occlusive member (mesh member 15 and tubular member 11) and an additional material of copper (column 8 lines 20-28). Referring to claim 16, Callister discloses a device that is microtextured by sandblasting (column 8 lines 13-15). Referring to claims 19 and 22, Callister also discloses a method that administers the composition including copper to occlude a vessel (see claims 33-42 and column 8 lines 25-28).

13. Claims 1 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,894,022 to Ji et al. Ji discloses the claimed vaso-occlusive composition. Ji discloses a matrix base (Column 2 lines38-42) that cross-links fibrin(column 11 lines 65-67) to form a microscopic mesh (column 2 lines 53-56).

14. Claims 1, 7, 8, 11, 17, 19 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,800,507 to Schwartz. Schwartz discloses the claimed vaso-occlusive composition. Referring to claims 1, 7 and 8, Schwartz discloses a composition that includes a vaso-occlusive member (column 4 lines 64-67) and thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44). Referring to claims 11 and 17, Schwartz discloses a composition that the material fibrin is

adsorbed to the vaso-occlusive member (column 3 lines 60-64) and the vaso-occlusive member has a tie layer between the stent and the material fibrin (column3 line 60 - column 4 line 4). Referring to claims 19 and 23, Schwartz discloses a method that administers a vaso-occlusive composition including the thrombus-stabilizing molecule Factor XIII (column 3 lines 43-44) to an occluded vessel (column 4 line 64 - column 5 line 5).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507. Schwartz discloses the claimed device except for the use of plasminogen activator inhibitor-1 (PAI-1) or α_2-antiplasmin as the thrombus-stabilizing molecule. It is well known that Factor XIII, PAI-1 and α_2-antiplasmin may all be utilized to prevent a thrombus from breaking up. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace Factor XIII (column 3 lines 47-48) with PAI-1 or α_2-antiplasmin, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

17. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507 in view of U.S. Patent No. 5,891,192 to Murayama et al. Schwartz discloses the claimed invention except for the vaso-occlusive member being subjected to ion implantation. Murayama teaches that ion implantation alters the surface properties of a metal implant such as thrombogenicity, endothelial

cellular migration and adhesion, minimally increases the dimensions of the implant, and increases the fixation of a protein coating on the metal surface of the implant (see Column 3 lines 21-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the metal stent of Schwartz '507 to include the application of ion implantation in order to change the surface properties including thrombogenicity, endothelial cellular migration and adhesion, minimally increase the dimensions of the stent, and to increase the fixation of the protein on the surface of the metal stent.

18. Claims 31, 32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,888,546 to Ji et al. in view of Ji et al.'022. Ji '546 discloses a vaso-occlusive composition comprising a vaso-occlusive member and a liquid embolic material (see Column 2 lines 30-37, Column 3 lines 61- Column 4 line 18), the particulate embolic material is selected from the group of consisting of microspheres, granules, and beads (see Column 2 line 64 –67, Column 3 lines 18-22), the composition further comprising an additional bioactive material selected from the group of at least one cytokine, extracellular matrix material, DNA, RNA, functional fragments of DNA and RNA, cytokines or extracellular matrix material (Column 4 line 65- Column 5 line 6, Column 5 lines 23-59), the liquid embolic material is biodegradable (see Column 4 lines 57-62, Column 9 lines 11-16). Ji '546 discloses a method comprising administering the vaso-occlusive composition (see Column 3 line 61 – Column 4 line 3). Ji '546 discloses the claimed invention except for the use of a coil as the vaso-occlusive member. Ji '022 teaches that a coil is used to hold an injected material in place by the use of a wire coil. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include the coil of Ji '022 as part of the occlusive member of Ji '546 in order to hold the liquid material in position.

Response to Arguments

19. Applicant's arguments filed 12/2/02 have been fully considered but they are not persuasive.

20. Regarding the argument that Eder '550 includes three components and has more elements than the claimed invention, Eder's water soluble coating includes the use of at least one cytokine (growth factors), which makes the outer coating of Eder part of the bioactive material as claimed (Column 5 line 64- Column 6 line 15). Therefore the rejection over Eder '550 is proper.

21. Regarding the argument that Callister '052 includes more than the required number of components of the claimed invention, applicant argues that there is an extra mesh. That mesh is considered part of the vaso-occlusive member. Therefore, the rejection over Callister '052 is proper.

22. Regarding Ji '022, applicant argues that the composition in Ji '022 is not vaso-occlusive. However, Ji '022 specifically discloses that his compositions are used for occlusive purposes (Column 3 lines 17-27). Therefore the rejection over Ji '022 is proper.

23. Regarding Schwartz '507, applicant argues that the stent of Schwartz may not be used to occlude a vessel since it is designed to prevent occlusion. Schwartz teaches that his stent may be used to seal aneurysms (Column 4 line 64 – Column 5 line 5). Although a stent is typically used to prevent occlusion, Schwartz specifically states that it can be used to occlude. In addition, a stent is placed on the inside of a vessel, so it is inherently going to occlude the diameter of the vessel in to which is it placed. Therefore, the rejection over Scwartz '507 is proper.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter
Examiner
Art Unit 3731

jrb
February 6, 2003

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